Policy Number: 2.7

Policy Title: Reviewing Protocols with Food and Fluid Restrictions, Non-Pharmaceutical Grade Compounds, or Prolonged Restraint

Section 1: Purpose

The purpose of this policy is to outline the procedure for reviewing animal use protocols (AUPs) involving food and/or fluid restrictions, non-pharmaceutical grade compounds, or prolonged restraint.

Section 2: Scope

This policy applies to all AUPs in the review process that contain food and/or fluid restrictions, non-pharmaceutical grade compounds, or prolonged restraint.

Section 3: Policy

Food and Fluid Restrictions

The IACUC should review protocols involving food and/or fluid restrictions for the following:

- The food and/or fluid restriction is scientifically justified.
- The least restriction necessary to achieve the study objectives is used.
- The potential adverse effects from the restriction have been considered.
- Methods for assessing the health and well-being of animals are defined.
- Criteria have been established for the temporary or permanent removal of an animal from the study if health and wellbeing are negatively impacted by the restriction to an unacceptable level.

Non-Pharmaceutical Grade Substances

The IACUC should review protocols involving non-pharmaceutical grade substances for the following:

- No pharmaceutical grade equivalents are available. Cost is not a justification for the use of non-pharmaceutical grade substances in lieu of pharmaceutical grade.
- The use of the substance is scientifically justified.
- The substance is safe and effective.

Prolonged Physical Restraint

The IACUC should review protocols involving prolonged physical restraint for the following:

- Prolonged restraint is necessary to achieve objectives of the study and is scientifically justified.
- Restraint devices that will be used are appropriate in size, design, and operation to minimize discomfort, pain, distress, and the potential for injury to the animal and the research staff.
• Animals will be provided training to restraint devices and provisions have been made in the event an animal is not able to adapt to the device.
• The study includes observations of restrained animals at appropriate intervals.

The IACUC may require additional provisions on a case by case basis to ensure the welfare of animals that are undergoing prolonged restraint.